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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Leigh, Steve et. al.

Application No.: 10/670,504

Filing Date:

September 26, 2003

Group Art Unit: 2854

Examiner:

Confirmation No.: 8609

Title: Method and Composition for Solubilising a Biologically Active Compound with Low Water Solubility

# FIRST INFORMATION DISCLOSURE STATEMENT TRANSMITTAL LETTER

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Enclosed is a FIRST Information Disclosure Statement and accompanying form PTO-1449 for the above-identified patent application.  No additional fee for submission of an IDS is required.  The fee of \$180.00 (1806) as set forth in 37 C.F.R. § 1.17(p) is also enclosed.  A statement under 37 C.F.R. § 1.97(e) is also enclosed.  A statement under 37 C.F.R. § 1.97(e), and the fee of \$180.00 (1806) as set forth in 37 C.F.R.	
The fee of \$180.00 (1806) as set forth in 37 C.F.R. § 1.17(p) is also enclosed.	
§ 1.17(p) are also enclosed.  Charge to Deposit Account No. 02-4800 for the fee due.  A check in the amount of is enclosed for the fee due.  The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 at 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in duplicate.	and <sub>.</sub>
Respectfully submitted,  BURNS, DOANE, SWECKER & MATHIS, L.L.P.	
P.O. Box 1404 Alexandria, Virginia 22313-1404 (703) 836-6620  Patrick C. Keane Registration No. 32,858	



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For:

Method and Composition for Solubilising)

a Biologically Active Compound with

Low Water Solubility

#### FIRST INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure as set forth in 37 C.F.R. § 1.56, the accompanying information is being submitted in accordance with 37 C.F.R. §§ 1.97 and 1.98.

Pursuant to 37 C.F.R. § 1.98, a copy of each of the documents cited is enclosed. However, copies of the listed U.S. patents and U.S. patent application publications are not enclosed since it is no longer required according to the July 11, 2003 waiver of the requirement for copies of cited U.S. patents and U.S. patent application publications in national patent applications filed after June 30, 2003 and international applications entering the national stage under 35 U.S.C. § 371 after June 30, 2003.

The documents are being submitted within three (3) months of the filing or entry of the national stage of this application or before the first Office Action on the merits, whichever is later. Since these documents are being filed within the time period set forth in 37 C.F.R. § 1.97(b), no fee or statement is required.

The relevance of these documents is their citation in the specification and/or their citation in a PCT International Search Report, received in connection with what is believed to be a foreign counterpart application to the present application. A copy of the PCT Search Report dated February 5, 2003 is also enclosed.

FIRST Information Disclosure Statement Application No. 10/670,504
Attorney's Docket No. 032553-037
Page 2

To assist the Examiner, the document is / documents are listed on the attached form PTO-1449. It is respectfully requested that an Examiner initialed copy of this form be returned to the undersigned.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

Date And 1, LOOY

P.O. Box 1404 Alexandria, Virginia 22313-1404 (703) 836-6620 By:

Patrick C. Keane

Registration No. 32,858

Substitute for form 1	449A/PTO 8	1449B/PTC

Sheet

### **FIRST** INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary) of

Complete if Known				
Application Number	10/670,504	IPE		
Filing Date	September 26, 200			
First Named Inventor	Leigh, Steve et. al			
Examiner Name		APR 0 1 2004		
Attorney Docket Number	032553-037	\B		
,		THADEWARK		

•			U.S. PATENT DOCUMENTS	
Examiner Initials	Document Number	Kind Code	Name of Patentee or Applicant of Cited Document	Issue/Publication Date (MM-DD-YYYY)
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	5,091,188		Haynes	May 5, 1998
	5,747,066		Pittrof et al	June 19, 1979
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		Date of Publicati			Trans	
Examiner	Document	Kind Code	Country	(MM-DD-YYYY)	Yes	No
Initials	Number	(if known)	WIPO	Sept. 7, 1988		
	WO88/06442			March 30, 2000		X
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	WO98/58629		WIPO	Oct. 9, 1986		·
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	NON-PATENT LITERATURE DOCUMENTS
Examiner Initials	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.  Isele, U.; Van Hoogevest, P.; Hilfiker, R.; Capraro, H-G.; Schieweck, K. and Leuenberger, H., Large-Scale Production of Liposomes Containing Monomeric Zinc Phthalocyanine by Controlled Dilution of Organic Solvents, J. Pharm. Sci. (1994), 83, 1608-1616  Gopi K. Vudathala and James A. Rogers, Dissolution Of Fludrocortisone From Phospholipid Coprecipitates, J. Pharm. Sci. 81, 283-286 (1992).

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		Date	
Examiner		Considered	" " " it and in it not in
Signature	Initial if reference considered, whether or not citation is in c	onformance with M.P.E.	P. § 609. Draw line through citation is not in
*CVANINED	. Initial if reference considered, whether of not challen is in	to Analizant	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.